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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,633	02/14/2001	Steven R. Bailey	6006-009	2694

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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

NOTIFICATION DATE	DELIVERY MODE
02/20/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

scotugno@biopatentlaw.com

Office Action Summary	Application No.	Applicant(s)	
	09/783,633	BAILEY ET AL.	
	Examiner	Art Unit	
	CHERYL MILLER	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *68-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 68-71 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 68-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 68 recites the limitation "detection mechanism configured to *measure*", emphasis added, which is considered new matter. Applicants "detection mechanism" appears to be imaging devices such as radiography, ultrasonography, magnetic resonance imaging, etc, which *detect* or *display* an image, however does not appear to *measure* parameters. Claims 69-76 depend upon claim 68 and inherit all problems associated with the claim.

Claim Objections

Claim 70 is objected to because of the following informalities: The claim seems to be incomplete (does not contain a period and is possibly missing limitation previously recited). Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 68-72 and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by Santini, Jr. et al. (US 2004/0260391 A1). Santini discloses an in vivo sensor device system (stent; seen in fig.9a-9c) comprising a plurality of structural elements (individual struts of stent OR caps of individual microchips seen in fig.9a) defining the device, the structural elements (struts or microchip caps) composed of a first material having either a transitional temperature or coefficient and at least one region of the structural elements composed of a second material having a transitional temperature or coefficient higher than the first material (different microchip caps made of different materials with different transitional temperatures or deform at different rates, P0030, P0048, P0046), the geometry or conformation capable of changing (expansion of stent changes conformation, as does melting or pressure on caps, causes conformation change of caps/microchips) upon application of a force (heat, pressure, etc). The stent is responsive to pressure or temperature thus considered to measure the parameters. Santini discloses a detection mechanism (console, monitoring system, P0090, P0091).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 68-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmeister (EP 0 759 730 B1, cited previously) in view of Wolinsky et al. (US 6,840,956 B1). Regarding claim 68, Burmeister discloses an in vivo sensor device system (stent 30; seen in fig.3) comprising a plurality of structural elements (individual struts, configuration of stent 30 examples seen in figs.8-11; P0049) defining the device, the structural elements (struts) composed of a first material (austenite shape memory material 32) having either a transitional temperature or coefficient and at least one region (outer surface region; see fig.3) of the structural elements composed of a second material (martensite superelastic material 34) having a transitional temperature or coefficient higher than the first material (see fig.4a, 4b showing transitional temperature greater for material 34; P0029, P0032), the geometry or conformation capable of changing (expansion seen in figs.8b, 9b, 10b, 10d, 11b; P0036) upon application of a force (heat, pressure, etc). Burmeister discloses the system substantially as claimed, however is silent to mention any detection mechanisms for measuring the geometry/conformation change (expansion). Wolinsky teaches in the same field of stents (16; fig.2), the use of a detection mechanism (fluoroscopy; col.6, lines 12-15) in order to view the insertion, position and expansion of the stent to insure the stent was implanted correctly. Such imaging techniques are well known in the stent art. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Burmeister's stent system with Wolinsky's teaching of using fluoroscopy (detection mechanism) with the implantation of stents, in order to provide a system that provides the surgeon with assistance and reassurance that the stent was positioned

accurately in the vessel (as fluoroscopy views the stent during expansion, it also displays the structural elements/struts changing configuration).

Referring to claims 69-71, Burmeister discloses the first material to comprise a shape memory material and the second material to comprise a superelastic material, wherein the second material has a higher martensite transition temperature (see fig.4b compared to fig.4a).

Referring to claims 72-75, Burmeister's sensor (stent 30) is configured to monitor a condition such as pressure (pressure is created by fluid flow or plaque build-up) or temperature (stent changes shape when expanded in response to pressure or temperature, P0030, P0032, P0012, thus is considered to "monitor" these parameters).

In an alternative to the above rejection, claims 72-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmeister (EP 0 759 730 B1, cited previously) in view of Wolinsky et al. (US 6,840,956 B1). Burmeister in view of Wolinsky discloses the system substantially as claimed (see above rejection with respect to claim 68). Burmeister does not however disclose an in vivo sensor (stent 30) configured to monitor a physiological condition such as flow rate, temperature, plaque, or electrochemical charge. Wolinsky teaches in the same field of stents (16), the use of an additional element (12) attached to the stent, configured to monitor the physiological conditions claimed (col.4, lines 48-60), in order to detect early signs of potential problems for prevention (col.6, lines 44-52). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Burmeister in view of Wolinsky's stent system with Wolinsky's teaching of monitoring elements in order to provide a system that is capable of detecting problems early such that they may be prevented or fixed at an early stage.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738